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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/574,842

04/06/2006

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EXAMINER

PAGE, BRENT T

ART UNIT

PAPER NUMBER

1638

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/574,842	Applicant(s) BAE ET AL.	
	Examiner BRENT PAGE	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/06/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's election without traverse of Group I, claims 1-8 in the reply filed on 06/27/2008 is acknowledged.

Drawings

The drawings are objected to because Figure 1 does not contain any reference to SEQ ID NO:1. Either the Brief Description of figures needs to contain the reference to SEQ ID NO:1, or corrected drawings are required. If the brief description of Figures is not amended, corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a specified, full-length promoter of the ibAGP1 gene of sweetpotato, does not reasonably provide enablement for any sequences from the region or any sequence derived from the gene that act as a sucrose inducible promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to an isolated plant sucrose-inducible promoter sequence comprising any sequence of a 1907 base region specified by SEQ ID NO:1, an isolated 5' untranslated region of a sweetpotato ADP-glucose pyrophosphorylase gene comprising any sequence of a 67 base region specified by SEQ ID NO:1, a binary vector, a transient expression vector, an E. coli, and a plant, all comprising said sequences.

In contrast, the specification only gives guidance for the full-length 1907 base region, and in combination with the 67 base region for use as a sucrose inducible promoter, and does not give guidance for using any other sequences that contain as little as 2 bp of SEQ ID NO:1 as a sucrose inducible promoter.

The function of promoter fragments and sequence variants in transgenic plants is unpredictable. Kim et al (1994, Plant Molecular Biology 24:105-117) in a mutational analysis of the nopaline synthase promoter in a stable transformation system, found that mutation of a single nucleotide significantly altered the strength of expression, while deletions in other regions of the promoter completely eliminated function (page 108 first full paragraph).

Deletion analysis of promoters is unpredictable. Donald et al (1990, EMBO J. 9:1717-1726) teach that a crucial promoter element for the *Arabidopsis* rcbS-1A promoter is located in the region about 250 bases upstream of the transcription initiation site.

Furthermore, the function of promoter fragments and sequence variants in transgenic plants is unpredictable wherein the promoter function is regulated by conditional elements. Dolferus et al (1994, Plant Physiology 105:1075-1087) in a deletion analysis of the *Arabidopsis* *Adh* promoter, found that deletion of different elements of the promoter affected promoter function conditional to the stress that was applied to the given promoter fragment (page 1080, last full paragraph and page 1082 first full paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate all promoter-effective molecules that comprise 2bp of SEQ ID NO:1 for function as a sucrose inducible promoter as broadly claimed. To obviate this rejection, the claims should be amended to recite comprising ---the--- DNA nucleotide

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sequence of ---the--- -1 to -1908 region if applicants intended to claim only the full-length sequence. New Matter should be avoided.

Claims 1-8 and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated plant sucrose-inducible promoter sequence comprising any sequence of a 1907 base region specified by SEQ ID NO:1, an isolated 5' untranslated region of a sweetpotato ADP-glucose pyrophosphorylase gene comprising any sequence of a 67 base region specified by SEQ ID NO:1, a binary vector, a transient expression vector, an E. coli, and a plant, all comprising said sequences.

In contrast, the specification only describes the full-length 1907 base region, and in combination with the 67 base region for use as a sucrose inducible promoter, and does not describe the use of any other sequences that contain as little as 2 bp of SEQ ID NO:1 as a sucrose inducible promoter. The specification does not describe the structural elements that are required for the claimed function (sucrose inducible promoter). The working examples only describe the use of the full length promoter from sweetpotato ADP-glucose pyrophosphorylase.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a

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precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

To obviate this rejection, the claims should be amended to recite comprising --- the--- DNA nucleotide sequence of ---the--- -1 to -1908 region if applicants intended to claim only the full-length sequence. New Matter should be avoided.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Siedlecka et al (2003 In Planta 217:184-192).

The claims are drawn to an isolated plant sucrose-inducible promoter sequence comprising any sequence of a 1907 base region specified by SEQ ID NO:1 and wherein the sequence is "derived" from an ibAGP1 gene of sweetpotato.

Siedlecka et al teach a sucrose inducible promoter of the small subunit ADP-glucose pyrophosphorylase of Arabidopsis and the transformation of plants with said promoter which would inherently comprise "a" DNA nucleotide sequence of a bp -1 to -

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1908 region from SEQ ID NO:1. The term “derived” is relative terminology and is being interpreted to mean having some relationship to the sequence, which the promoter taught by Siedlecka et al inherently has since the promoter is from the same gene.

Claims 3-8 and 11-12 are free of the prior art given the failure of the prior art to teach or reasonably suggest a 5' untranslated region of the sweetpotato ADP-glucose pyrophosphorylase gene or vectors comprising both a sucrose inducible promoter and said 5' untranslated region and transformed plants therefrom. The prior art also fails to teach or reasonably suggest sucrose inducible promoters that may be amplified from the primers recited in claims 11-12.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Anne Marie Grunberg/

Supervisory Patent Examiner, Art Unit 1638